UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,935	02/05/2003	Roger Inouye	B0662/7036	2561

23628 7590 10/04/2004

WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,935	INOUYE ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanA as the antisense molecule).

Group II, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanR as the antisense molecule).

Group III, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanS as the antisense molecule).

Group IV, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanH as the antisense molecule).

Group V, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanX as the antisense molecule).

Group VI, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanY as the antisense molecule).

Group VII, claim(s) 1-6, 10-19, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanA organisms and vanZ as the antisense molecule).

Group VIII, claim(s) 1-5 and 7, 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms only and vanRB as the anti-sense molecule).

Group IX, claim(s) 1-5, 7 and 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms and vanSB as the antisense molecule).

Group X, claim(s) 1-5, 7 and 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms and vanYB as the antisense molecule).

Group XI, claim(s) 1-5, 7 and 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms and vanW as the antisense molecule).

Group XII, claim(s) 1-5, 7 and 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms and vanHB as the antisense molecule).

Group XIII, claim(s) 1-5, 7 and 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanB organisms and vanXB as the antisense molecule).

Group XIV, claim(s) 1-5 and 8, 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanC organisms only).

Group XV, claim(s) 1-5 and 9, 13-15, drawn to a method for reducing vancomycin resistance in a vancomycin-resistant organism (generic claims and vanD organisms only).

Group XVI, claim(s) 20-23, drawn to a method for reducing vancomycin resistance by enhancing the expression of a vanH promoter in the organism, etc....

Group XVII, claim(s) 24-29, drawn to isolated nucleic acid molecules, vectors and host cells comprising said molecules. **NOTE: if this Group is selected Applicants must elect a single sequence identifier to which the nucleic acid hybridizes, e.g. SEQ ID NO:2**. This is a Restriction Requirement, not a species election.

Groups I-XVII do not relate to a single general inventive concept because according to Rule 13 PCT an application must relate to one invention only or to a group

of inventions so linked as to form a single general inventive concept, i.e. having at least one common technical feature defining a contribution over the known prior art. In the present case, the special technical feature is considered to be (i) a method for reducing vanomycin resistance in a vancomycin-resistant organisms using different antisense sequences to inhibit expression of a vancomycin resistance gene. (ii) The special technical feature of isolated nucleic acid sequences that hybridize under stringent conditions to a nucleic acid sequence conferring vancomycin resistance (in particular to SEQ ID Nos 1-13, preferably SEQ ID Nos 5-13 and more preferably SEQ ID No 5-10) (antisense sequences) are also claimed. However, the nucleic acid sequences responsible for vancomycin (VanA, VanB, Vanc and VanD) resistance were already well known in the prior art as well as nucleic acid sequences hybridizing to these sequences and general fragments and/or portions thereof (see International Search Report, in particular W092/07942). Thus, in view of this prior art, the second common technical feature cited above (ii) cannot be seen as a single inventive concept anymore. The general use of antisense antibiotic resistance molecules for inhibiting the expression of an antibiotic resistance gene and thus, reducing antibiotic resistance in an antibiotic-resistant organism was also well-known in the prior art (WO90/0O624) (ii). This antisense approach had been disclosed as being useful for general antibiotic resistance and particularly referred in connection with vanomycin resistance too (see P. Mitchell, Pharmaprojects Magazine 1998,Vol. 3(8), 16-20). Moreover, (parts of) isolated nucleic acid sequences that hybridize under stringent conditions to a nucleic acid sequence conferring vancomycin resistance had already been used for inactivating (insertion by

homologous recombination) or reducing the vancomycin resistance in a vancomycin resistant organism (W092/07942). Thus, neither the use of general antisense molecules nor the reduction of the vancomycin resistance in a vancomycin-resistant organism can be considered as a single inventive concept. The underlying technical problem of the present invention is considered to be the provision of alternative methods for reducing vancomycin resistance and the (antisense) products therefore. Each and every group of the inventions identified above provide a particular and specific solution to this technical problem. However, due to the mechanism of action and the structural differences among the different products used in each one of these above identified groups of inventions, there is no common technical feature defining an inventive contribution over the known prior art. Furthermore, the IPEA supports this lack of unity of invention and even the further subdivision of isolated nucleic acids hybridizing to the different components of the corresponding Van resistances (vanA, vanR, vans, vanH, vanRB, vansB, etc...) of the VanH promoter and these different components of the Van resistances.

2. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

9/29/04